REMARKS

Claims 1-124, and 126-165 are pending the application. Claims 1-123, 125, 128-162 and 165 have been canceled. Claims 126 and 127 have been withdrawn. Applicants hereby expressly reserve their right to prosecute the canceled and withdrawn claims in a separate application. Claims 124, 163-164 has been amended to more clearly define what applicants claim as the invention. Claims 166-175 have been newly added.

Claim 1 was amended to recite "A method of reducing inflammation in gene therapy" Support can be found at least in paragraph [0116] of the published application where vectors used in gene therapy are disclosed.

Claim 1 was also amended to recite "administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector". Support can be found at least in paragraph [0124] of the published application where vectors comprising a complement modulator displayed on the surface of a vector is disclosed.

Claims 163 and 164 were amended to recite proper dependency as necessitated by the amendment to claim 124.

Newly added claim 166 was added to recite "The method of claim 124, wherein the complement modulator comprises two repeats of ED1 and a linker." Support can be found at least in paragraph [0122] of the published application.

Newly added claim 167 was added to recite "The method of claim 166, wherein the complement modulator further comprises a His-tag." Support can be found at least in paragraph [0122] of the published application.

Newly added claim 168 was added to recite "The method of claim 124, wherein the complement modulator comprises SEQ ID NO:9." Support can be found at least in paragraph [0122] of the published application.

Newly added claim 169 was added to recite "The method of claim 124, wherein the complement modulator comprises the ed1 region of the Sh-TOR protein of Schistosoma parasite." Support can be found at least in paragraph [0121] of the published application.

Newly added claim 170 was added to recite "The method of claim 124, wherein the viral vector further comprises a gene of interest." Support can be found at least in paragraph [0230] of the published application.

Newly added claim 171 was added to recite "The method of claim 124, wherein the viral vector further comprises a targeting motif." Support can be found at least in paragraph [0140] of the published application.

Newly added claim 172 was added to recite ") The method of claim 171, wherein the targeting motif is selected from the group consisting of the tripeptide RGD sequence, fifber-fibritin chimeras, CD40L, E-selectin targeting peptides, and SSTR-avid peptide." Support can be found at least in paragraphs [0104] – [0108] of the published application.

Newly added claim 173 was added to recite "The method of claim 124, wherein the viral vector further comprises a promoter." Support can be found at least in paragraphs [0108] – [0109] of the published application.

Newly added claim 174 was added to recite "The method of claim 124, wherein the viral vector further comprises a reporter nucleic acid.." Support can be found at least in paragraphs [0111] – [0112] of the published application.

Newly added claim 174 was added to recite "The method of claim 124, wherein the viral vector further comprises a CAR binding site mutation or an ablation of integrin-binding." Support can be found at least in paragraph [0118] of the published application.

Abstract

Applicants have provided a clean page amendment with the same abstract.

Claim Objections

Claim 164 was objected to under 37 CFR 1.75(c) all allegedly being of improper dependent form. Applicants submit that claim 164 has been amended to depend from amended claim 124. With the amendment, Applicants respectfully submit that the objection is moot and request that the objection be withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 165 was rejected under 35 U.S.C §112, second paragraph as allegedly being indefinite for depending from a cancelled claim. Applicants submit that claim 165 has been cancelled. Therefore, Applicants respectfully submit that the objection is moot and request that the objection be withdrawn

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 124, 130-134, and 152-165 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action alleges that the

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Specifically, the Office Action admits that the specification is enabling for operably-linked expression control sequences comprising a promoter to the encoded protein sequence, does not reasonably provide enablement for an absence of an operably-linked promoter or the simple operable linkage of any expression control element. Applicants respectfully traverse these allegations to the extent that they apply to the claims as currently amended.

Applicants first note that claims 130-134, and 152-162 and 165 have been canceled. As such, Applicants submit that the rejection of these claims is moot.

Applicants further note that claims 124 and 163-164 have been amended. Claim 124 was amended to recite "A method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator displayed on the surface of the vector, wherein the complement modulator inhibits complement activation." Claims 163 and 164 were amended to depend from Claim 124, and therefore, by definition include all limitations of claim 124.

The rejection under 35 U.S.C. 112, first paragraph appears to, in part, take issue with the presence or absence of an operably-linked promoter. Specifically, the Office Action provides that "Claim 161 indicates that all the broader claims do not require an operably-linked promoter" (See Office Action page 5, lines 3-6). Applicants respectfully submit that amended claims 124, 163 and 164 are not drawn to nucleic acid sequences. Claims 124, 163 and 164 claim, in part, administering a composition comprising a viral vector comprising a complement modulator displayed on the surface of the vector, thereby making no reference to expression control

elements. At least for this reason, Applicants submit that the present claims are fully enabled and that the present rejection does not provide persuasive evidence or argument to the contrary. Accordingly, the present rejection should be withdrawn.

The Office Action also alleges that the confluence of Applicants' specification fails to teach nucleic acids which inhibit complement activation, or even modulate inflammation.

Applicants would like to point out that in order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support (MPEP 2164.04).

Here, the Office Action has merely made an unsupported statement that "the Art fails to teach" nucleic acids which inhibit complement activation, or even modulate inflammation. The Office Action cites nothing other than a blanket statement that such a teaching fails to exist and that the Artisan would hav eto experiment to determine the coding sequences themselves act to inhibit inflammation. Applicants submit that such an unsupported statement fails to meet the mandated burden described above..

Applicants would also like to point to the MPEP (Section 2164.02), which states that,

"The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)." This is certainly the case here.

As provided above, Claim 124 has been amended administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector. In other words, claim 124 is not drawn to a nucleic acid complement modulator. As required by the claims, the complement modulator is displayed on the surface of the vector. Complement modulators are defined in paragraph [0079] of the instant specification and examples are provided throughout the specification with experimental examples provided throughout the "EXAMPLES" section of the specification. Specifically, Examples 16 and 17 show the ability to construct and use viral vectors expressing a complement modulator on the surface of the vector to decrease complement activation and thereby reduce toxicity and immune response to gene therapy vectors. Applicants submit that these Examples in combination with the other 15 Examples provided in the specification expressly teach how to both construct and use the viral vectors currently claimed as well as teaching complement modulators that reduce inflammation in gene therapy or that inhibit complement activation.

For all of the above reasons, applicants submit that the present claims are fully enabled and that the present rejection does not provide persuasive evidence or argument to the contrary. Accordingly, the present rejection should be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 124, 152, 160 and 161 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, 160 and 161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claim 124 as amended is pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

Amended claim 124 (as well as the amended and new claims depending from claim 124) claims a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation. As such, claim 124 requires, in part, administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector. Applicants respectfully submit that Mason et al. fails to teach such a method or composition.

Mason et al. teaches modified retroviral producer cells producing retroviral particles for facilitating gene therapy procedures involving the transduction of target cells with retroviral vector particles in the presence of complement containing body fluids. The genetic alterations comprise the introduction of nucleic acid expression constructs directing the expression of retroviral SU (gp70)/complement inhibitor chimeric proteins into cells from which the producer cells are derived. In other words, the methods described by Mason et al. require transduction of

target cells by viral particles carrying a complement inhibitor sequence that must be incorporated into the target cell genome. Once the complement modulator is incorporated into the target cell genome, the target cell can express the complement modulator, which is then responsible for inhibiting or affecting complement. Thus, at most, Mason et al. teaches administering viral particles carrying a nucleotide sequence capable of encoding a complement modulator, but depends on the transduction of a target cell and the subsequent expression of the complement inhibitor by the target cell. This is not what is claimed an is significantly different than the claimed invention.

As described above, Claim 124 claims a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation. As such, claim 124 requires, in relevant part, administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector. Nowhere in Mason et al. is there any teaching, motivation or suggestion of administering such a composition, nor even creating such a composition as currently claimed, namely a viral vector comprising a complement modulator expressed on the surface of the vector.

The Office Action relies on the Summary of Invention and the first three paragraphs of Mason et al. for support. Applicants do not currently take issue with the statements regarding vectors that contain nucleic acid sequences capable of encoding a complement inhibitor, but Applicants again submit that retroviral vectors carrying a nucleic acid sequence capable of encoding a complement inhibitor is not the same as a viral vector comprising a complement

modulator expressed on the surface of the vector.

As such, the methods taught by Mason et al. do not teach a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation. As such, Mason et al. fails to disclose every feature of the claimed methods.

Because Mason et al. fails to disclose every feature of the claimed methods, Mason et al. fails to anticipate claim 124 and the claims dependent therefrom. As such, Applicants respectfully request withdrawal of this rejection.

Rejection Under 35 U.S.C. § 103

1. Claims 124, 152, 160, 161 and 163 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24) and U.S. Patent No. 7,468,181 to Vogels, et al. ("Vogels, et al."). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, 160 and 161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124 and 163 as amended are pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in

the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Xing et al. discloses expression of the gal epitope on the surfaces of human tumor cell lines after adenoviral vector transduction. In other words, Xing et al. is similar to that which is taught by Mason et al., namely expressing a peptide by or on a target cell (See Xing et al., page 117, column 1, 2nd full paragraph).

Vogels et al. discloses methods and means for the production of adenoviral vectors on complementing cell lines. The Office Action cites paragraph 6 under the Detailed Description of Vogels et al. for allegedly describing the addition of peptides to several surface displayed proteins of adenoviruses. Applicants submit that the portion of Vogels et al. cited by the Office Action, at best, is directed to linking or fusing targeting moieties to a viral particle. This is not what is claimed. Claim 124 specifically requires that the complement modulator is expressed on the surface of the viral vector. Applicants submit that linking a peptide to the surface of a viral particle is not the same as expressing a complement modulator on the surface of a viral vector.

Furthermore, the Office Action alleges that it would be obvious to modify Mason et al. to utilize adenoviral vectors and further to use adenoviral vectors for administration and to avoid complement mediated inactivation. Applicants do not agree with such a leap of reasoning. Mason et al. is very specific in their use of vectors to deliver a complement inhibitor by relying on the target cells expression of the inhibitor. As described above, nowhere does Mason et al. disclose of suggest modifying the viral vector itself to express a complement modulator. The

Office Action relies on Vogels et al. to provide a teaching or suggestion to utilize a viral vector to display a peptide on the surface of a viral vector. Applicants submit that such a reliance is fatally flawed. Nowhere in Vogels et al. is there any discussion of expressing a complement modulator on the surface of a viral vector. While Vogels et al. may provide a description of linking a peptide to a viral particle, Vogels et al. does not teach or suggest incorporating a a complement modulator sequence into the genome of a viral vector such that the complement modulator is expressed by and on the surface of the viral vector. Xing et al. certainly does not provide any such teaching or suggestion either. The only teaching of such a method lies in the current specification, and therefore the Office Action, in order to reach the claimed invention, must rely on impermissible hindsight to reach the claimed method and compositions.

Thus, Mason et al., Xing et al. and Vogels et al., either alone or in combination, fail to disclose or suggest each and every element of claims 124 and 163. As such, Applicants respectfully request withdrawal of the rejection.

2. Claims 124, 152, 160, and 160-163 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24), U.S. Patent No. 7,468,181 to Vogels, et al. ("Vogels, et al.") and in further view of U.S. Patent No. 6,127,525 to Crystal et al. ("Crystal et al"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, and 160-162 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124 and 163 as amended are pending. As such, Applicants provide the following Response to the extent that the

rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Applicants note that the rejection applies Mason et al., Xing et al. and Vogels et al., in the same way and for the same disclosure for which Mason et al. was applied in the rejection under 35 U.S.C. § 102 above and Mason et al., Xing et al. and Vogels et al. were applied in the rejection under 35 U.S.C. § 103. For at least the reasons discussed above in connection with the rejections under 35 U.S.C. § 102 and §103, Mason et al., Xing et al. and Vogels et al. fail to disclose or suggest every limitation of claim 124. Specifically, Mason et al., Xing et al. and Vogels et al. fail to disclose or suggest a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation.

Crystal et al. which was cited for allegedly demonstrating that several hypervariable regions of adenovirus may be deleted and/or substituted with chimeric peptides does not make up for the deficiencies found in Mason et al., Xing et al. and Vogels et al. Applicants note that claim 163 depends from claim 124, and therefore contains all the limitations of claim 124. Thus, Mason et al., Xing et al., Vogels et al., and Crystal et al. either alone or in combination, fail to

disclose or suggest each and every element of claims 124 and 163. Applicants respectfully request withdrawal of the rejection.

3. Claims 124, 152, 160, and 161 and 163 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24), U.S. Patent No. 7,468,181 to Vogels, et al. ("Vogels, et al."), U.S. Patent No. 6,127,525 to Crystal et al. ("Crystal et al") and in further view of Inal, et al. (2000, FEBS Letters, 470: 131-134). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, and 160-161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124 and 163 as amended are pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Applicants note that the rejection applies Mason et al., Xing et al., Vogels et al. and Crystal et al., in the same way and for the same disclosure for which Mason et al. was applied in the rejection under 35 U.S.C. § 102 above and Mason et al., Xing et al., Vogels et al. and Crystal et al. were applied in the rejection under 35 U.S.C. § 103. For at least the reasons discussed

above in connection with the rejections under 35 U.S.C. § 102 and §103, Mason et al., Xing et al., Vogels et al. and Crystal et al. fail to disclose or suggest every limitation of claim 124. Specifically, Mason et al., Xing et al., Vogels et al. and Crystal et al. fail to disclose or suggest a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation.

Inal et al. which was cited for allegedly teaching that the ED1 domain of Sh-TOR inhibits complement and does so when isolated from the normal protein does not make up for the deficiencies found in Mason et al., Xing et al., Vogels et al. and Crystal et al. Applicants note that claim 163 depends from claim 124, and therefore contains all the limitations of claim 124. Thus, Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. either alone or in combination, fail to disclose or suggest each and every element of claims 124 and 163. Applicants respectfully request withdrawal of the rejection.

4. Claims 124, 152, 160, and 161 and 163 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24), U.S. Patent No. 7,468,181 to Vogels, et al. ("Vogels, et al."), U.S. Patent No. 6,127,525 to Crystal et al. ("Crystal et al") Inal, et al. (2000, FEBS Letters, 470: 131-134) and in further view of Huang et al. (2000, Protein Expression and Purification, 18: 169-174). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, and 160-161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124 and 163 as

amended are pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Applicants note that the rejection applies Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. in the same way and for the same disclosure for which Mason et al. was applied in the rejection under 35 U.S.C. § 102 above and Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. were applied in the rejection under 35 U.S.C. § 103. For at least the reasons discussed above in connection with the rejections under 35 U.S.C. § 102 and §103, Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. fail to disclose or suggest every limitation of claim 124. Specifically, Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. fail to disclose or suggest a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation.

Huang et al. which was cited for allegedly teaching isolating His-Tagged entities using the His-Tag does not make up for the deficiencies found in Mason et al., Xing et al., Vogels et al., Crystal et al. and Inal et al. Applicants note that claim 163 depends from claim 124, and

therefore contains all the limitations of claim 124. Thus, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. either alone or in combination, fail to disclose or suggest each and every element of claims 124 and 163. Applicants respectfully request withdrawal of the rejection.

4. Claims 124, 152-154 160, and 161 and 163 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24), U.S. Patent No. 7,468,181 to Vogels, et al. ("Vogels, et al."), U.S. Patent No. 6,127,525 to Crystal et al. ("Crystal et al") Inal, et al. (2000, FEBS Letters, 470: 131-134), Huang et al. (2000, Protein Expression and Purification, 18: 169-174) and in further view of Oh et al., (2003, Immunology, 110:73-79). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152-154, and 160-161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124 and 163 as amended are pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Applicants note that the rejection applies Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. in the same way and for the same disclosure for which Mason et al. was applied in the rejection under 35 U.S.C. § 102 above and Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. were applied in the rejection under 35 U.S.C. § 103. For at least the reasons discussed above in connection with the rejections under 35 U.S.C. § 102 and §103, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. fail to disclose or suggest every limitation of claim 124. Specifically, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. fail to disclose or suggest a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation.

Oh et al. which was cited for allegedly teaching that a duplicated ED1 domain provides increased inhibition of complement activation over that of a single ED1 domain does not make up for the deficiencies found in Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al. and Huang et al. Applicants note that claim 163 depends from claim 124, and therefore contains all the limitations of claim 124. Thus, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. either alone or in combination, fail to disclose or suggest each and every element of claims 124 and 163. Applicants respectfully request withdrawal of the rejection.

5. Claims 124, 152, 160, 161, 163 and 164 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,770 to Mason, et al. ("Mason et al."), in view of Xing et al. (2001 Cell Research, 11(2): 116-24), U.S. Patent No. 7,468,181 to Vogels, et al.

("Vogels, et al."), U.S. Patent No. 6,127,525 to Crystal et al. ("Crystal et al") Inal, et al. (2000, FEBS Letters, 470: 131-134), Huang et al. (2000, Protein Expression and Purification, 18: 169-174), Oh et al., (2003, Immunology, 110:73-79), and in further view of Goncalves et al (2001, Virology, 288(2):236-46). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Applicants first note that claims 152, and 160-161 have been canceled and therefore submit that the rejection is moot with respect to these claims. However, Claims 124, 163 and 164 as amended are pending. As such, Applicants provide the following Response to the extent that the rejection applies to the claims as amended.

In order for a reference or a combination of references to anticipate a claim or claims, "[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Applicants note that the rejection applies Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. in the same way and for the same disclosure for which Mason et al. was applied in the rejection under 35 U.S.C. § 102 above and Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. were applied in the rejection under 35 U.S.C. § 103. For at least the reasons discussed above in connection with the rejections under 35 U.S.C. § 102 and §103, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. fail to disclose or suggest every limitation of claim 124. Specifically,

Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. fail to disclose or suggest a method of reducing inflammation in gene therapy in a subject, comprising administering a composition comprising a viral vector comprising a complement modulator expressed on the surface of the vector, wherein the complement modulator inhibits complement activation.

Goncalves et al. which was cited for allegedly teaching encapsulation of AAV vectors into Adenoviral envelopes does not make up for the deficiencies found in Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al. and Oh et al. Applicants note that claims 163 and 164 depend from claim 124, and therefore contains all the limitations of claim 124. Thus, Mason et al., Xing et al., Vogels et al., Crystal et al., Inal et al., Huang et al., Oh et al. and Goncalves et al. either alone or in combination, fail to disclose or suggest each and every element of claims 124, 163 and 164. Applicants respectfully request withdrawal of the rejection.

A credit card payment is being submitted via EFS Web in the amount of $65.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(1), together with a Request for One Month Extension of Time. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No.14-0629.

Respectfully submitted,

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